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Hypoxic corneal changes following 8 hours of scleral contact lens wear

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Abstract

Purpose: To examine the change in corneal thickness and posterior curvature following 8 hours of miniscleral contact lens wear.

Methods: Scheimpflug imaging (Pentacam HR, Oculus) was captured before, and immediately following, 8 hours of miniscleral contact lens wear for 15 young (mean age 22 ± 3 years), healthy participants with normal corneae. Natural diurnal variations were considered by measuring baseline corneal changes obtained on a separate control day without contact lens wear.

Results: Over the central 6 mm of the cornea, a small, but highly statistically significant amount of edema was observed following 8 hours of miniscleral lens wear, after accounting for normal diurnal fluctuations (mean ± standard deviation percentage swelling 1.70 ± 0.98%, $p < 0.0001$). Posterior corneal topography remained stable following lens wear (-0.01 ± 0.07 mm steepening over the central 6 mm, $p = 0.60$). The magnitude of posterior corneal topographical changes following lens wear did not correlate with the extent of lens-related corneal edema ($r = -0.16$, $p = 0.57$). Similarly, the initial central corneal vault (maximum post-lens tear layer depth) was not associated with corneal swelling following lens removal ($r = 0.27$, $p = 0.33$).

Conclusions: While a small amount of corneal swelling was induced following 8 hours of miniscleral lens wear (on average <2%), modern high Dk miniscleral contact lenses that vault the cornea do not induce clinically significant corneal edema or hypoxic related posterior corneal curvature changes during short-term wear. Longer-term studies of compromised eyes (e.g. corneal ectasia) are still required to inform the optimum lens and fitting characteristics for safe scleral lens wear to minimize corneal hypoxia.

Keywords: Miniscleral contact lens, corneal edema, posterior corneal curvature, hypoxia

Introduction

Scleral contact lenses are primarily used for the correction of irregular corneal optics (e.g. keratoconus) or as a therapeutic intervention for ocular surface disease (e.g. Sjogren's syndrome) since the post-lens tear layer not only neutralises corneal astigmatism and irregularity, but provides constant corneal lubrication. Prior to the advent of rigid gas permeable (RGP) scleral lenses,[1] short periods of poly-methyl methacrylate (PMMA) scleral lens wear (3-5 hours) induced clinically significant corneal edema which was managed through modifications such as flattening the haptic zone (to increase edge lift and promote tear exchange) or lens fenestrations.[2] While modern scleral RGP contact lenses, made from highly oxygen permeable materials (typically a Dk of 90 × 10^{-11} [cm^2/s] [ml 0_2/mL × mmHg] or greater), induce significantly less corneal hypoxia, there is still some debate regarding the optimum (or minimum) scleral lens thickness, post-lens tear layer thickness, lens material oxygen permeability and lens fitting characteristics required to provide safe, non-hypoxic, scleral contact lens wear.[3]

A number of short-term clinical studies have attempted to quantify hypoxic changes (typically the change in central corneal thickness) as a result of scleral lens wear. Early studies of low Dk scleral RGP lenses worn for up to five hours during open eye conditions typically showed a level of corneal edema comparable to physiological overnight swelling or slightly greater, which decreased proportionally as lens thickness was reduced or oxygen permeability of the lens material was increased.[4,5] Mountford et al[6] reported that for hyper-Dk full scleral lens wear (Dk 120), corneal edema occurred at a rate of approximately 1 μm per hour, while overnight wear of scleral RGP's has been shown to induce significant corneal edema (5-18%)[7] and is typically not recommended unless therapeutically necessary.

Recently, several studies have examined the corneal response following short-term modern (high Dk) miniscleral contact lens wear.[8-10] Miniscleral lenses are smaller in diameter (15-18 mm) compared to full scleral lenses (up to 25 mm) and are becoming increasingly popular due to their relative ease of patient handling and practitioner fitting.[11] Although lens thickness, material oxygen permeability and clinical techniques (i.e. the measurement of corneal edema) varied between these experiments, on average, central corneal swelling was minimal, typically below 4%. These clinical studies appear to be consistent with reports of relatively low hypoxia-related complication rates associated with modern scleral lens wear,[12] however, such low levels of corneal edema contradict a number of theoretical models concerning oxygen delivery to the cornea during scleral lens wear.[9,13,14]

While it has been shown that the cornea reaches a steady state of swelling following 3 hours of lens wear or exposure to a hypoxic environment,[15,16] it is important to examine the corneal response following a longer duration of scleral lens wear, since scleral lens fits can vary substantially over time. Following insertion, scleral lenses gradually sink into the ocular tissues overlying the sclera (the conjunctiva, episclera and Tenon's capsule)[17] and the post-lens tear layer diminishes (by ~80-140 μm over 8 hours),[18] which presumably influences tear exchange and oxygen delivery to the cornea. Additionally, patients who wear scleral lenses rely on them for either optimal visual correction or corneal rehabilitation and often wear the lenses for several hours a day (over 70% of scleral lens wearers report wearing times of 8 hours or more per day[12]). In this study, we build on previous work examining hypoxia-induced changes in corneal pachymetry and posterior corneal topography following short-term (3 hour) miniscleral lens wear by substantially increasing the duration of lens wear to 8 hours in a cohort of young adults with normal corneae in order to provide more clinically relevant measures of scleral lens-induced hypoxia.

Methods

This study was approved by the Queensland University of Technology (QUT) human research ethics committee and followed the tenets of the Declaration of Helsinki. All subjects gave written informed consent to participate. The study participants included 15 young, healthy adult subjects (8 females, 7 males; 8 Asian, 7 Caucasian) recruited from the QUT School of Optometry and Vision Science aged between 18 and 32 years (mean ± SD age: 22 ± 3 years) with visual acuity of 0.00 logMAR or better. Prior to commencement of the study, all subjects were screened to exclude those with any contraindications to contact lens wear (i.e. significant tear film or anterior segment abnormalities). Four of the subjects were part-time soft contact lens wearers but discontinued lens wear for 24 hours prior to commencing the study, to minimize the effects of soft lens wear on the cornea. None of the subjects were previous RGP contact lens wearers. Participants had no prior history of eye injury, surgery or current use of topical ocular medications. Sample size calculations using previously published data on corneal swelling following short-term scleral lens wear, suggested that a sample size of greater than 10 participants would yield 80% power to detect 2% corneal edema[5] at the 0.05 significance level.

Experimental overview

Changes in corneal thickness and posterior corneal topography following 8 hours of miniscleral contact lens wear were examined using Scheimpflug imaging. The study was conducted over three separate days; day one involved an ophthalmic screening and miniscleral contact lens fitting, day two included baseline diurnal corneal measurements obtained without contact lens wear and day three involved the capture of corneal measurements before and after miniscleral contact lens wear. On day two, baseline measurements were obtained without contact lens wear, in the morning (between 8:00 and 10:00 AM) and then repeated 8 hours later (between 4:00 and 6:00 PM). On day three, the subjects wore the optimal fitting diagnostic miniscleral contact lens (according to the manufacturers fitting guide) in their left eye only, with measurements collected in the morning before the lens was inserted (between 8:00 and 10:00 AM) and again, immediately after lens removal following 8 hours of lens wear (between 4:00 and 6:00 PM). The timing of the measurement sessions for days two and three were matched for each participant to allow for the control of the confounding influence of diurnal variation[19] during analysis. Participants were free to go about their daily activities between the morning and afternoon measurement sessions. Day 2 baseline measurements (without contact lens wear) were captured at least 48 hours after the initial contact lens fitting (on day 1) to minimize the potential influence of any ocular surface changes associated with the initial scleral lens fitting process.

Contact lens assessment

Irregular Corneal Design (ICD™ 16.5, Paragon Vision Sciences, USA) contact lenses were used for this study. These are non-fenestrated miniscleral lenses made from hexafocon A material (Boston XO) with a Dk of 100, central thickness of 300 μm and overall diameter of 16.5 mm. The optimal fitting diagnostic contact lens was determined according to the manufacturers fitting guide. The initial trial lens was selected based on the participants corneal sagittal height measured over a 10 mm chord (along the steepest corneal meridian) using a videokeratoscope (E300, Medmont, Australia) which was then extrapolated to a 15 mm chord (i.e. the distance to the landing zone of the ICD lens) by adding 2000 μm to the 10 mm chord sag value. An additional 400 μm was then added to this sag value to allow for an initial central corneal vault of between 300-400 μm. The lens was inserted into the participants left eye with preservative free saline and sodium fluorescein, without an air bubble present, and assessed using a slit lamp biomicroscope. The fluorescein pattern was assessed to ensure adequate central corneal clearance and sufficient limbal clearance to observe sodium fluorescein bleed beyond the limbus to the conjunctiva. If regions of corneal bearing were observed, the sagittal depth of the lens was increased (in 100 μm increments) and the fit reassessed. After an adequate initial fit was obtained, the lens was then allowed to settle for one hour, and was re-examined using the slit lamp. The contact lens fit was assessed during the trial lens fitting (with sodium fluorescein) and on the day of lens wear (without sodium fluorescein) to ensure the lens was centred and free from any air bubbles. The limbal clearance zone and the scleral landing zone were not modified, and during the experiment all participants wore the diagnostic trial lens which provided an adequate fit according to the manufacturers fitting guide.

Anterior segment imaging

The Pentacam HR system (Oculus, Wetzlar, Germany), a rotating Scheimpflug camera, was used to evaluate the corneal thickness and posterior corneal curvature at each measurement session. Five error free measurements were captured using the 25 picture 3D scan mode, which provides 25 cross-sectional images of the anterior eye. This instrument provides measurements of corneal thickness and posterior corneal topography with repeatability limits of 4 ± 12 μm for thickness measurements at the corneal apex and 0.03 ± 0.08 mm for posterior radius of curvature.[20] Following lens insertion on day 3, and after 8 hours of lens wear, the central corneal clearance was measured using a spectral domain optical coherence tomographer with an anterior segment module attachment (RS-3000, Nidek, Japan). A high resolution 6 mm radial line protocol was used (12 line scans separated by 30 degrees) centred on the corneal reflex, visualised in the scanning laser ophthalmoscope image. The callipers within the analysis software were used to mark the position of the back surface of the miniscleral contact lens and the anterior surface of the corneal epithelium to provide a measure of the central corneal clearance at the position of the corneal reflex along both the horizontal and vertical corneal meridians. The mean central corneal clearance was 353 ± 131 μm following lens insertion and 258 ± 119 μm after 8 hours of lens wear.

Data analysis

Following data collection, the raw corneal curvature and pachymetry data from all five measurements on each participant, at each time point, were exported for further analysis. Using custom written software, the five maps obtained for each participant were averaged for each time point. The baseline data obtained on day 2, without contact lens wear, was then used to calculate the normal diurnal change in each corneal parameter (thickness and posterior curvature) by subtracting the mean morning measurement (8:00-10:00 AM) from the mean afternoon measurement (4:00-6:00 PM) for each participant.

The same procedure was then used to examine the influence of miniscleral contact lens wear upon the cornea. The mean day 3 pre-lens wear morning data was subtracted from the mean day 3 afternoon data (after 8 hours of lens wear) for each participant. To eliminate the potential confounding influence of diurnal variations, the normal diurnal fluctuations calculated from the day 2 baseline data were also subtracted to generate 'difference' data (the change in corneal parameters immediately following lens removal) which provides the changes due to lens wear only. All analyses presented in this manuscript refer to these data that have been corrected for normal diurnal variations in corneal parameters.

The average maps from all participants were further analysed in order to study the regional distribution of corneal change. To examine the statistical significance of changes after 8 hours of miniscleral contact lens wear, a repeated measures analysis of variance (ANOVA) was used with three within-subject factors of time (pre and post lens wear), corneal region (8 corneal segments from 0-360° in 45° increments) and corneal annuli (6 annuli from 0-6 mm in 1 mm increments). Degrees of freedom were adjusted using Greenhouse-Geisser correction to prevent any type 1 errors, where violation of the sphericity assumption occurred. Bonferroni adjusted post-hoc pair-wise comparisons were carried out for individual comparisons if indicated. Pearson's correlation coefficient was used to quantify the association between the changes in corneal thickness and posterior curvature changes in the central (0-3 mm) and 'peripheral' (3-6 mm) corneal regions and also the change in corneal thickness with the central corneal clearance (i.e. the thickness of the post-lens tear layer after lens insertion on day 3). All statistical analyses were conducted with SPSS (version 21.0) statistical software and results are reported as mean and standard deviations.

Results

Corneal Pachymetry

After accounting for natural corneal diurnal variations, the magnitude corneal swelling following 8 hours of miniscleral contact lens wear was, on average, less than 2% (Table 1). The mean increase in corneal thickness over the central 6 mm was 10.23 ± 5.77 μm (1.70 ± 0.98% swelling), which did not vary substantially between the central 0-3 mm of the cornea 10.02 ± 5.75 μm (1.72 ± 1.00%) or the peripheral region (3-6 mm annulus, 10.44 ± 5.85 μm [1.69 ± 0.93%]) (Figure 1). While this extent of corneal swelling was highly statistically significant ($p < 0.0001$), the corneal edema observed in this study would not be considered clinically significant given that overnight eyelid closure induces approximately 4% of physiological edema.

There were no significant time by corneal region ($p = 0.19$), time by corneal annuli ($p = 0.15$) or time by corneal region by corneal annuli ($p = 0.09$) interactions, which suggests that the level of corneal swelling observed following miniscleral lens wear was relatively uniform across the central 6 mm of the cornea. No participants exhibited corneal swelling greater than 4% after lens removal, with the maximum level of edema observed in any participant being 2.96%, averaged over the central 6 mm.

Posterior corneal curvature

Posterior corneal curvature remained stable following 8 hours of miniscleral contact lens wear, with a mean change over the central 6 mm of -0.01 ± 0.07 mm (p = 0.60). While the magnitude of change in posterior curvature vaired slightly with corneal region (Figure 2, difference map) with segments 4-7 (135 to 315 degrees) displaying greater posterior corneal steepening compared to segments 1-3 (0 to 135 degrees) which displayed posterior flatening on average, there was no time by corneal region interaction (p = 0.30) indicating that changes in posterior corneal topography following lens wear were similar between the 8 segments within the central 6 mm. There were also no time by annuli (p = 0.14) or time by region by annulus (p = 0.65) interactions.

Correlation analysis

Pearson's correlation analysis revealed no statistically significant association between the magnitude of corneal edema induced following lens wear and the magnitude of change in posterior corneal topography over the central 3 mm (r = 0.04, p =0.89), the central 6 mm (r = -0.16, p = 0.57) or the 3-6 mm peripheral annulus (r = -0.41, p = 0.13). No relationship was observed between the initial or final central corneal clearance (the thickness of the central post-lens tear layer) and the magnitude of post-contact lens wear corneal edema for the central 0-3 mm (initial r = 0.05, p = 0.86; final r = 0.02, p = 0.94), the central 0-6 mm (initial r

= 0.27, $p = 0.33$; final $r = 0.07$, $p = 0.80$) or the 3-6 mm peripheral annulus (initial $r = 0.16$, $p = 0.57$; final $r = 0.15$, $p = 0.59$).

Discussion

This is the first study to examine, in detail, the regional changes in both corneal thickness and posterior curvature (as markers of hypoxic corneal stress) following 8 hours of modern high Dk miniscleral contact lens wear taking into consideration the normal diurnal fluctuations in these corneal parameters. All of our participants were young and healthy with normal corneae and no history of ocular disease or scleral lens wear. Consequently, the results must be interpreted with caution, and may not be applicable for older patients or those with ocular disease or abnormal corneae (e.g. keratoconus or compromised endothelium).

Statistically significant corneal swelling was observed following high Dk miniscleral lens wear ($p < 0.0001$); however, the mean magnitude of edema over the central 6 mm was 1.70 ± 0.98%, and well within the magnitude of physiological corneal swelling associated with overnight eyelid closure, or edema associated with 8 hours wear of older generation soft lens materials (e.g. 3.7% swelling observed with hydroxyethyl methacrylate [HEMA][21]). The superior-nasal cornea displayed a slightly greater magnitude of corneal swelling compared to other corneal regions (Figure 1), which might be expected due to the position of the upper eyelid acting as a physical barrier to atmospheric oxygen; however, there were no statistically significant regional variations in the corneal response across the central 6 mm examined. Changes in posterior corneal topography, typically a central flattening, have been associated with corneal swelling for various contact lens types.[21,22] No statistically significant changes in posterior corneal topography occurred following lens removal, in agreement with the minimal corneal edema observed following lens removal (Figure 2).

Hypoxic stress associated with scleral lens wear has been hypothesised to occur due to a thick and stagnant post-lens tear layer and the substantially thicker lenses required to minimize flexure (compared to corneal RGP lenses). However, while PMMA scleral lens wear was associated with significant hypoxia-related corneal complications (corneal neovascularisation in 13% and corneal edema in 7% of patients[23]), such complications are uncommon in RGP scleral lens wear (a 1.3% failure rate due to corneal neovascularisation or edema),[12] which suggests that oxygen levels reaching the cornea during modern scleral lens wear are sufficient for most patients. The finding of a low level of corneal edema following 8 hours of high Dk miniscleral contact lens wear in the current study is consistent with some recent work examining corneal changes following modern scleral lens wear of shorter duration. Vincent et al[8] and Frisani et al[10] reported less than 1% of corneal swelling, measured objectively using a Scheimpflug camera, following 3-5 hours of miniscleral lens wear (Dk of 92-100, center lens thickness of 260-300 μm, and mean central corneal clearance of <200 to 400 μm) in young participants with normal corneae. Conversely, Compan et al[9] observed a mean of 1.66% to 4.27% corneal swelling following three hours of lens wear with a very similar miniscleral lens (Dk of 100, central corneal clearance of either 150 or 350 μm) and cohort (young participants with normal corneae). The substantially greater level of edema observed by Compan et al[9] may be related to the manual contact technique used to measure pachymetry (which also required corneal anaesthesia, known to influence corneal thickness) which relies upon clinician accuracy to assess corneal thickness at the same location (centred on the corneal reflex) before and after lens wear. An alternative possibility is that the true thickness of the post-lens tear layer was substantially underestimated by the slit-lamp estimation technique and the software simulation used by the authors (i.e. corneal vault was not quantitatively measured). Soeters et al[24] also observed minimal decrease in corneal thickness of keratoconic patients following cessation of full scleral lens wear for 1-2 weeks, typically less than 4% (95% CI: 1.68 to 4%),for a range of lens designs (85-160 Dk and 18-22 mm diameter).

A number of theoretical models have been proposed concerning the oxygen supply to the cornea during scleral contact lens wear.[9,13,14] These static models vary, but typically consider scleral lens thickness and material oxygen permeability, the post-lens tear layer thickness and the oxygen content of these tears. Based on these theoretical calculations, it has been suggested that in order to minimize hypoxia-induced corneal swelling as a result of scleral contact lens wear, lenses should made of the highest oxygen permeable materials available and fitted without excessive corneal vault (i.e. less than 200 μm[14]). However, in the current study, following eight hours of high Dk miniscleral lens wear with a mean central vault value of well over 200 μm (~350 μm), clinically significant corneal edema was not induced. There was also no association between the initial post-lens tear layer and the magnitude of corneal swelling following lens removal, which suggests that the amount of corneal vault does not significantly contribute to corneal hypoxia in the short-term for healthy eyes. This supports clinical reports that patients can successfully wear scleral contact lenses with a substantial post-lens tear layer (up to 600 μm vault, mean 380 μm).[25]

Aside from scleral lens properties (e.g. lens thickness and material oxygen permeability) and fitting characteristics (e.g. the post-lens tear layer thickness profile, edge lift and compression associated with scleral landing curves) there are a number of other factors which may play a role in the regulation of corneal edema during scleral lens wear including; the endothelial pump mechanism, endothelial cell integrity or regularity which diminishes with age[26,27] and long-term contact lens wear,[28] the magnitude of negative pressure generated behind the lens,[29] blinking frequency and eyelid tension in relation to tear exchange,[2] and conjunctival compressibility with respect to lens sink and potential seal off.[17]

Recent proposed models[9,13,14] generated to predict oxygen levels reaching the cornea during scleral contact lens wear are static and do not account for dynamic changes that occur during lens wear such as; tear exchange (i.e. fresh oxygenated tears from outside the scleral lens pumped into the post-lens tear layer), tear mixing (i.e. the circulation of tears trapped within the post-lens tear layer), the thinning of the post-lens tear layer during lens wear, the lens/post-lens tear layer thickness away from the center of optic zone (the lens and post-lens tear layer are thickest centrally) or the duration of lens wear. Some of these factors may explain why theoretical models of oxygen levels reaching the cornea during scleral lens wear are not consistent with the results of short-term experimental studies and longer term clinical reports of minimal hypoxia-related complications in scleral lens wearers.

A methodological limitation of our study was the need to remove the contact lens to obtain accurate measures of corneal thickness. Pentacam imaging was conducted immediately following lens removal, and on average took 4 minutes and 11 seconds to obtain 5 error-free measurements. We calculated the change in corneal thickness between the first and fifth Pentacam image obtained after lens removal, which revealed a thinning of 3.72 ± 9.17 μm (0.66 ± 1.50 % thinning) averaged over the central 6 mm ($p = 0.14$). Therefore, the time taken between lens removal and the completion of the Pentacam measurements would result in a slight underestimation in the true amount of corneal edema. Previous studies have reported rebound corneal thinning following miniscleral contact lens wear,[8] and therefore alternative imaging techniques to measure corneal thickness with the lens on eye, such as anterior OCT, could be considered for future studies.

This study demonstrated that, on average, 8 hours of miniscleral lens wear does induce more corneal edema than that observed following three hours of lens wear,[8] despite previous research demonstrating a steady-state of corneal swelling following three hours of induced corneal hypoxia.[15,16] Therefore, greater changes in corneal edema may be apparent following longer periods of lens wear (e.g. greater than 8 hrs, or daily wear for weeks or months), or in patients with compromised or older corneae with reduced endothelial function, which requires further investigation.

Conclusion

A low level of corneal edema was observed immediately following 8 hours of miniscleral contact lens wear (1.70%), less than that typically observed following overnight eyelid closure. Posterior corneal topography remained stable following lens removal which supports the suggestion that the cornea did not experience clinically significant hypoxia during lens wear. Thickness and curvature changes did not vary significantly over the central 6 mm of the cornea, suggesting a consistent, symmetrical response. Modern high Dk miniscleral contact lenses do not induce clinically significant corneal edema following 8 hours of lens wear in young healthy participants with normal corneae.

Conflicts of interest

The authors have no financial interest in any of the products mentioned in the manuscript. Some of the data in the manuscript was presented at the 15th International Cornea and Contact Lens Congress, Gold Coast, Australia, 22 May – 24 May 2015.

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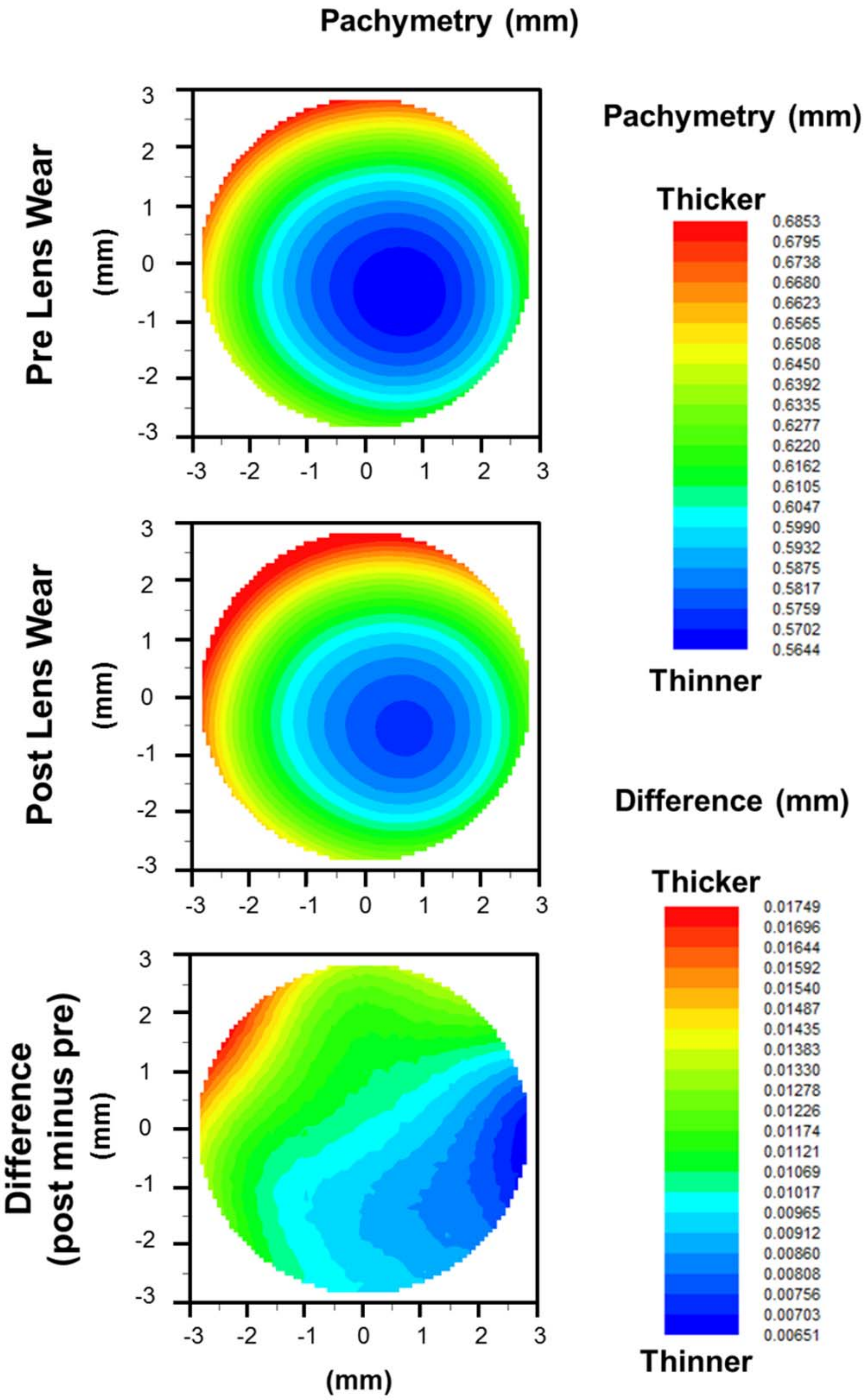

Figure 1. The group mean corneal thickness for the fifteen participants left eye measured over the central 6 mm before (top), immediately following 8 hours of miniscleral lens wear (middle) and the difference map (post minus pre-lens wear) after acounting for natural diurnal fluctuations in corneal thickness measured on a separate control day. Statistically significant, but clinically insignificant, corneal swelling was obsvered following lens removal.

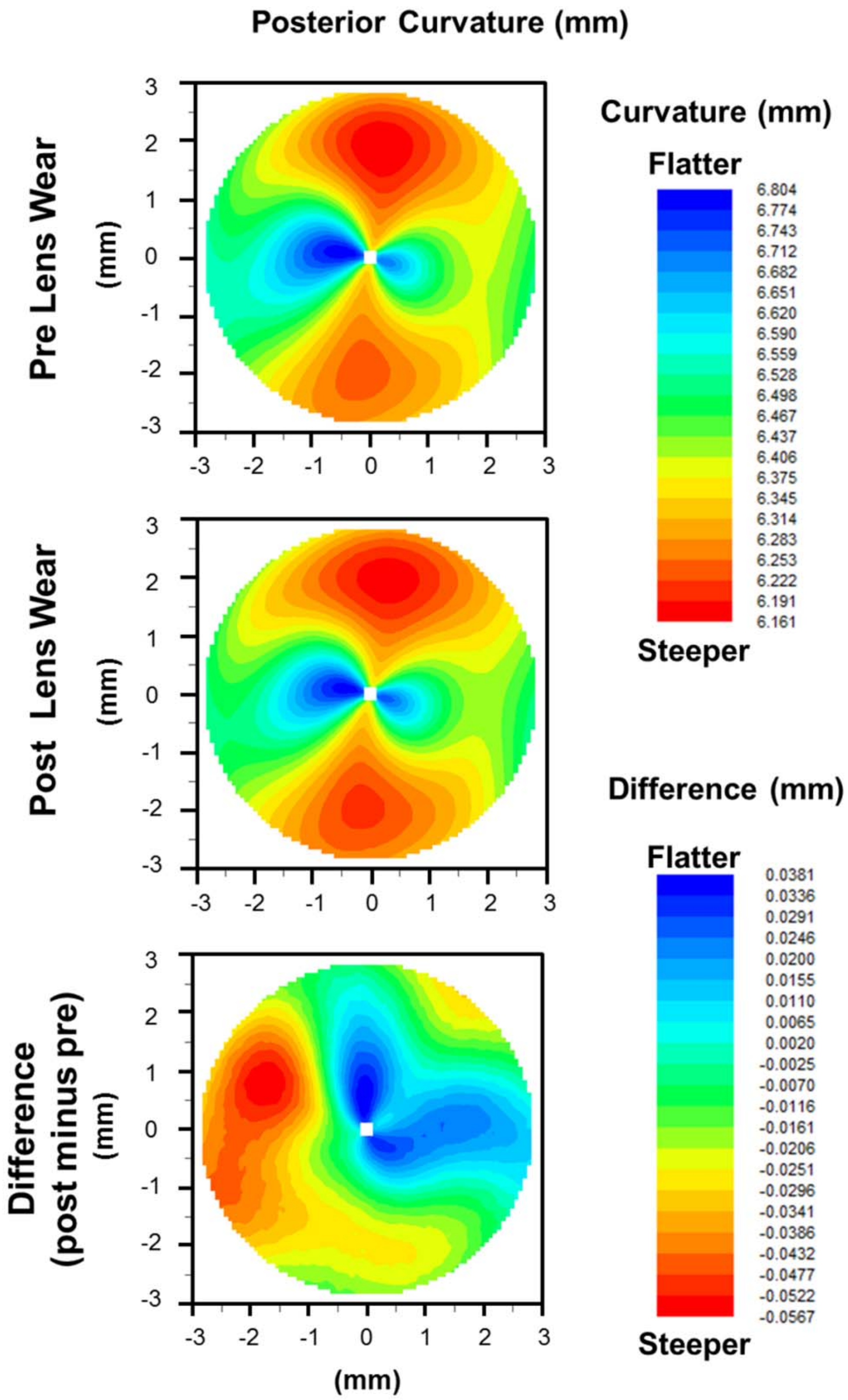

Figure 2. The group mean posterior corneal topography for the fifteen participants left eye measured over the central 6 mm before (top), immediately following 8 hours of miniscleral lens wear (middle) and the difference map (post minus pre-lens wear) after acounting for natural diurnal fluctuations measured on a separate control day. There were no statistically significant changes in posterior corneal topography.

Table 1: Mean ± SD corneal thickness averaged over the central 6 mm before and after 8 hours of miniscleral contact lens wear and the difference observed for the eight regions examined (mean ± SD and range).

CORNEAL REGION (°)	PRE-LENS WEAR (μm)	POST-LENS WEAR* (μm)	DIFFERENCE (μm)	
			MEAN ± SD	RANGE (min, max)
0-45	585 ± 41	594 ± 44	9 ± 6	-3, 21
45-90	600 ± 41	611 ± 43	11 ± 6	-1, 20
90-135	614 ± 41	626 ± 43	12 ± 6	0, 20
135-180	615 ± 41	627 ± 43	13 ± 7	-1, 22
180-225	606 ± 40	618 ± 42	12 ± 7	-2, 24
225-270	597 ± 39	608 ± 41	10 ± 7	-7, 21
270-315	588 ± 38	597 ± 41	9 ± 9	-8, 26
315-360	579 ± 38	588 ± 42	9 ± 7	-3, 23

* Post-lens wear corneal thickness values have been adjusted for natural diurnal corneal thinning measured on the Day 2 control day without lens wear